

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Summary of Changes between Proposed Rule and Final Rule LSA #15-39

Changes are highlighted

1. In 410 IAC 1-2.5-75(b), added the language “Except for HIV infection/disease, the” at the beginning of the first sentence and added the last sentence, which states “The report for HIV infection/disease shall be made directly to the department in accordance with IC 16-41-2-3.” These changes were made in response to a comment made by Angela M. Toth from The Corydon Group. Ms. Toth commented that the language of 410 IAC 1-2.5-75 requires reporting of HIV cases to the local health officer while IC 16-41-2-3 requires reporting to the state department of health and that the rules should be consistent and transparent with the statutes. These changes should fix this issue by requiring that HIV be reported directly to the state department of health pursuant to IC 16-41-2-3 (page 16 of final rule).

(b) **Except for HIV infection/disease, the** report required by subsection (a) shall be made to the local health officer in whose jurisdiction the patient normally resides or, in the absence of such information, in whose jurisdiction the patient was examined at the time the diagnosis was made or suspected. If the patient is a resident of a different jurisdiction, the local health jurisdiction receiving the report shall forward the report to the local health jurisdiction where the patient resides. If the patient is not a resident of Indiana, the report shall be forwarded to the department. If a person who is required to report is unable to make a report to the local health officer within the time mandated by this rule, a report shall be made directly to the department within the time mandated by this rule. **The report for HIV infection/disease shall be made directly to the department in accordance with IC 16-41-2-3.**

2. In 410 IAC 1-2.5-75(d), deleted “to the local health officer” from the second line and the third line. Added “to the local health department” in the fourth line. Added the line “HIV infection/disease required to be reported to the department during evening, weekend, and holiday hours should be reported immediately to the after-hours duty officer at the department at (317) 233-1325.” These changes were made in response to a comment made by Angela M. Toth from The Corydon Group. Ms. Toth commented that the language of 410 IAC 1-2.5-75 requires reporting of HIV cases to the local health officer while IC 16-41-2-3 requires reporting to the state department of health and that the rules should be consistent and transparent with the statutes. These changes should fix this issue by requiring that HIV be reported directly to the state department of health pursuant to IC 16-41-2-3. The language that shows a strikethrough was deleted and the language in yellow highlight was added (page 17 of final rule).

(d) **The dangerous communicable diseases and conditions described in this subsection shall be reported within the time specified. Diseases or conditions that are to be reported immediately to the local health officer shall be reported by telephone or other**

instantaneous means of communication on first knowledge or suspicion of the diagnosis. Diseases that are to be reported within twenty-four (24) hours, seventy-two (72) hours, or five (5) business days shall be reported ~~to the local health officer~~ within twenty-four (24) hours, seventy-two (72) hours, or five (5) business days of first knowledge or suspicion of the diagnosis by telephone, electronic data transfer, other confidential means of communication, or official report forms furnished by the department. During evening, weekend, and holiday hours, those required to report **to the local health department** should report diseases required to be immediately reported to the after-hours duty officer at the local health department. **HIV infection/disease required to be reported to the department during evening, weekend, and holiday hours should be reported immediately to the after-hours duty officer at the department at (317) 233-1325.** If unable to contact the after-hours duty officer locally, or one has not been designated locally, those required to report shall file their reports with the after-hours duty officer at the department at (317) 233-1325.

3. In 410 IAC 1-2.5-75, chart of “Dangerous Communicable Diseases and Conditions”, changed the placement of the hyphen in the disease “Carbapenemase producing – carbapenem resistant Enterobacteriaceae (CP-CRE)” to “Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE)” for clarification purposes. This is the way the ISDH Laboratories and the ISDH Epidemiology Resource Center refers to the disease (page 18 of final rule).

Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE)

4. In 410 IAC 1-2.5-76(d)(10), changed the placement of the hyphen in the disease “Carbapenemase producing – carbapenem resistant Enterobacteriaceae (CP-CRE)” to “Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE)” for clarification purposes. This is the way the ISDH Laboratories and the ISDH Epidemiology Resource Center refers to the disease (page 22 of final rule).

(10) Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE).

5. In 410 IAC 1-2.5-76(f)(1) changed the placement of the hyphen in the disease “Carbapenemase producing – carbapenem resistant Enterobacteriaceae (CP-CRE)” to “Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE)” for clarification purposes. This is the way the ISDH Laboratories and the ISDH Epidemiology Resource Center refers to the disease.

Added the language “(≤ 21 mm for ertapenem), and meet one (1) of the following criteria:

- (A) Positive for carbapenemase production by a phenotypic test (e.g., Modified Hodge or Carba NP).
- (B) Nonsusceptible to at least three (3) carbapenem antibiotics with MIC ≥ 2 $\mu\text{g/ml}$ or zone diameter ≤ 22 mm (≤ 21 mm for ertapenem).
- (C) Positive for a carbapenemase gene marker.”

These changes were made in response to comments received by Mary Stepney and Claudia Dant wanting clarification of what isolates the labs needed to submit in the CP-CRE sections of the rule. The ISDH Laboratories believes these changes will clarify the rule. The changes are highlighted in yellow (page 24 of final rule).

(f) Laboratories shall submit all isolates of the following organisms to the department's microbiology laboratory for further evaluation within three (3) business days of isolation:

(1) Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE). Isolates include organisms that are nonsusceptible to at least one (1) carbapenem antibiotic with MIC ≥ 2 $\mu\text{g/ml}$ or zone diameter ≤ 22 mm

(≤ 21 mm for ertapenem), and meet one (1) of the following criteria:

(A) Positive for carbapenemase production by a phenotypic test (e.g., Modified Hodge or Carba NP).

(B) Nonsusceptible to at least three (3) carbapenem antibiotics with MIC ≥ 2 $\mu\text{g/ml}$ or zone diameter ≤ 22 mm (≤ 21 mm for ertapenem).

(C) Positive for a carbapenemase gene marker.

Only one (1) isolate that meets these criteria should be submitted if the same organism is repeatedly recovered from the same patient.

6. In 410 IAC 1-2.5-87, changed the placement of the hyphen in the disease “Carbapenemase producing – carbapenem resistant Enterobacteriaceae (CP-CRE)” to “Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE)” for clarification purposes in the title and also under subsection (a) and (b). This is the way the ISDH Laboratories and the ISDH Epidemiology Resource Center refers to the disease.

Added a subsection (a) and the language “(≤ 21 mm for ertapenem), and meet one (1) of the following criteria:

(1) Positive for carbapenemase production by a phenotypic test (e.g., Modified Hodge or Carba NP).

(2) Nonsusceptible to at least three (3) carbapenem antibiotics with MIC ≥ 2 $\mu\text{g/ml}$ or zone diameter ≤ 22 mm (≤ 21 mm for ertapenem).

(3) Positive for a carbapenemase gene marker.)
are listed in subsection (b).”

Added a subsection (b) and the language “(b) The specific control measures for carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE) are as follows:” Both of these changes were made in response to comments received by Mary Stepney and Claudia Dant wanting clarification of what isolates the labs needed to submit in the CP-CRE sections of the rule. The ISDH Laboratories believes that these changes will clarify the rule. The changes are highlighted in yellow (pages 33-34 of final rule).

410 IAC 1-2.5-87 Carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE); specific control measures

Authority: IC 16-19-3-4; IC 16-41-2-1

Affected: IC 16-41-2; IC 16-41-9

Sec. 87. (a) The specific control measures for carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE) (infectious agent: organisms that are nonsusceptible to at least one (1) carbapenem antibiotic with MIC ≥ 2 μ g/ml or zone diameter ≤ 22 mm (≤ 21 mm for ertapenem), and meet one (1) of the following criteria:

(1) Positive for carbapenemase production by a phenotypic test (e.g., Modified Hodge or Carba NP).

(2) Nonsusceptible to at least three (3) carbapenem antibiotics with MIC ≥ 2 μ g/ml or zone diameter ≤ 22 mm (≤ 21 mm for ertapenem).

(3) Positive for a carbapenemase gene marker.)

are listed in subsection (b).

(b) The specific control measures for carbapenemase-producing carbapenem-resistant Enterobacteriaceae (CP-CRE) are as follows:

(1) An investigation shall be performed by the local health officer within seventy-two (72) hours and include individuals who have shared a residence with the patient in an acute care or long term care facility.

(2) The facility shall initiate contact precautions for CP-CRE; additional precautions should be added if any other transmissible condition is present.

(3) Supplemental measures for a health care facility with CP-CRE transmission include the following:

(A) Refer to the most recent CRE Toolkit from the Centers for Disease Control and Prevention for patient and environmental management of CRE patients.

(B) Consider screening of patients to determine if epidemiologically linked.

(C) Consider chlorhexidine gluconate bathing.

(4) Case definition is established by the department.

(Indiana State Department of Health; 410 IAC 1-2.5-87)